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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/524,754	08/29/2005	Nikola Kirilov Kasabov	PEBL-01001US1 DBB	6902

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EXAMINER
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WHALEY, PABLO S

ART UNIT	PAPER NUMBER
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1631

DATE MAILED: 10/19/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

10/524,754

Applicant(s)

KASABOV ET AL.

Examiner

Pablo Whaley

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 29 August 2005.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-7 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-7 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 15 February 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### *CLAIMS UNDER EXAMINATION*

An action on the merits of Claims 1-7 follows.

### *PRIORITY*

Priority to US Application 60/403,756, filed 8/15/2002, has been acknowledged.

### *DRAWINGS*

Drawings filed 2/15/2005 have been accepted.

### *OBJECTIONS*

Claim 3 is objected to because of the following informalities: Claim 3 is grammatically incorrect, and should recite "a method for supporting a medical decision..." . Appropriate correction is required.

## **CLAIM REJECTIONS - 35 USC § 101**

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 1-4 and 7 are rejected under 35 U.S.C. 101 because these claims are drawn to non-statutory subject matter.

Claims 1-2 are directed to a medical decision support system comprising a processor, memory device (i.e. products), two inputs, and a program comprising an algorithm (i.e. process) in the same claim. Therefore, the instant claims are not statutory as they are directed to neither a "process" nor a "machine," but rather embrace or overlap two different statutory classes of invention [MPEP 2173.05(p)].

Claims 3-4 are directed to a method for "support a medical decision on a computer," which does not recite either a physical transformation of matter nor a practical application. Claim 7 is directed to a method for extracting relationship rules between sets of genes and clinical variables. Claim 3 recites steps generally directed to classifying and combining information, which are not necessarily physical steps and therefore also encompass non-physical (i.e. *in-silico*) methods. Claim 7 does not set forth any method steps. Therefore the instant claims do not result in a physical transformation of matter. Where a claimed method does not result in a physical transformation of matter, it may be statutory where it recites a concrete, tangible, and useful result (i.e. a practical application). However, as set forth above, claim 3 results in "combining said...genetic information and...clinical information into a predicted outcome." Therefore, no tangible result is communicated to a user such that it is useful to one skilled in the art. For the reasons set forth above, the claims are not statutory. For an updated discussion of statutory considerations with regard to non-functional descriptive material and computer-related inventions, see the Guidelines for Patent Eligible Subject Matter at 1300 OG 142, Annex IV, Nov. 22, 2005.

**CLAIM REJECTIONS - 35 USC § 112, 2<sup>nd</sup> Paragraph**

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-8 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 recites a system comprising a processor, memory device, inputs for acquiring gene expression data, and a program comprising an algorithm. It is unclear whether the claimed system is intended to comprise a product (i.e. process, memory device, etc.) or a process (i.e. program). It is noted that a single claim that recites both a product and the method steps for using product in the same claim are considered indefinite [MPEP 2173.05(p)]. Clarification is requested.

Claim 1 recites the limitations "an input for acquiring...data." It is unclear whether said "input" is a data item, a physical product, or a process. Classification is requested.

Claim 1 recites the limitations "a....classifier/predictor module." It is unclear whether said "module" is intended to be for classification, prediction, or both. Classification is requested.

Claim 1 recites the limitations "said input...associated with a...module." It is unclear what structural or physical limitation of the system is intended by the applicant. It is also unclear in what way said input is "associated" with said modules. Classification is requested.

Claim 1 recites the limitation "combination algorithm." As the specification does not define or fully and completely describe a "combination algorithm" for carrying out the intended

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function, it is unclear as to the metes and bounds of this limitation. Clarification is requested.

The Examiner has interpreted this limitation broadly for purposes of applying prior art.

Claim 3 recites “using a first classifier/predictor module...to provide...information” in step (a). It is unclear whether said “using” denotes an active method step, a further limitation of the instant method, or an intended use. If an intended use, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced. Clarification is requested.

Claim 3 recites “classifying...information...into a second classifier/predictor module” in step (b). It is unclear in what way said information is classified “into a...model.” Clarification is requested.

Claim 4 recites the limitation “EfuNN process.” The use of tradenames render claims indefinite as such names can change over time or may be used to refer to a plurality of different methods, and it is unclear what steps are intended to be encompassed by the tradenamed method. Clarification is requested.

Claim 7 recites the limitation “extracting relationship rules between...genes and...variables.” It is unclear as to the intended meaning of “relationship rules” in this context. Clarification is requested.

Claim 7 recites the limitation “for patients of a group substantially as herein described.” It is unclear in what way this limitation further limits the instant method. It is noted that no such “patients of a group” was described in claim 7 or elsewhere. Clarification is requested. Claim 2 and 6 are rejected as they depend from claims 1 and 5.

### **CLAIM REJECTIONS - 35 USC § 102**

The following is a quotation of the appropriate paragraphs of 35 U.S.C.102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-3 and 5-7 are rejected under 35 U.S.C. 102 (b) as being unpatentable over Barry et al. (Pat. No. 6,081,786, Issued: Jun. 27, 2000).

Barry et al. teach expert systems, methods, and computer program products (i.e. computer executable instructions) for analyzing patient data for guide in the selection of therapeutic treatments for complex disorders, as in instant claims 1, 3, and 5. More specifically, Barry et al. teach the following aspects of the instant invention:

- Multiple inputs for acquiring patient information (i.e. gene expression data) and clinical information (i.e. therapy history), an inference engine (i.e. program), and output [Fig. 2], as in instant claims 1, 2, 5, and 6.
- Patient information comprising phenotype information [Ref. Claim 4] and [Col. 5, Lines 3-5], which implicitly is a teaching for "gene expression" information as in instant claims 1, 3, 5, and 6. This is further supported by [www.answers.com](http://www.answers.com), which defines "gene expression" as the transcription, translation, and phenotypic manifestation of a gene.

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- The inference engine combines data inputs and selects the best treatment [Col. 13, lines 21-30] and [Fig. 11D], which is an implicit teaching for a “predicted outcome” as in instant claim 3 and 7.
- Listings (i.e. relationships) generated in the computing device based on the patient information and the expert rules [Col. 2, lines 60-65], which equates to “extracting relationship” between data sets as in instant claim 7.

Claims 1-7 are rejected under 35 U.S.C. 102 (b) as being unpatentable over Slonim et al. (Annual Conference on Research in Computational Molecular Biology, Proceedings of the fourth annual international conference on Computational molecular biology, 2000, p. 263 – 272)

Slonim et al. teach a method for classifying cancer by computational analysis of gene expression data [Abstract], as in instant claims 1-7. More specifically, Slonim et al. teach the following aspects of the instantly claimed invention:

- The computational analysis system of Slonim et al. [Abstract] is implicitly a teaching for a processor, memory device, and inputs, as in instant claims 1 and 5.
- Classification of gene expression data from leukemia samples using neighborhood analysis (i.e. first classifier) [p.268, Col. 1, ¶ 3 and 4], as in instant claims 1 and 3.
- Classification of T-cells and B-cells (i.e. clinical information) using a second predictor [p.268, Col. 2, ¶ 3], as in instant claims 1 and 3.
- Prediction of treatment success (i.e. predicted outcome) via correlation of classified gene expression and chemotherapy data (i.e. classified clinical information) [p.269, Col. 2, ¶ 1], as in instant claims 3 and 6.



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- Classification of cancerous from normal cell samples (i.e. clinical information) based off gene expression data [Fig. 2], as in instant claim 3 (c).
- Bayesian analysis is used for classification, prediction, and confidence testing on all data [p.267, Section 3.3], as in instant claim 4.
- Pair-wise comparison of gene expression and cancer data using clustering algorithms for class discovery, cluster validation, and prediction strength [p.269, Section 5], which is an alternative teaching for classifying and combining information as in instant claims 3 and 6.
- Graphs of correlations between genetic information and clinical data [Fig. 3 and 4], which equates to extracting relationship rules as in instant claim 7.

## CONCLUSION

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Pablo Whaley whose telephone number is (571)272-4425. The examiner can normally be reached on 9:30am - 6pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang can be reached at 571-272-0811. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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*12/16/06*